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VIA ECF

Hon. Theodore D. Chuang U.S. District Court for the District of Maryland 6500 Cherrywood Lane, Suite 245A Greenbelt, MD 20770

Re: American College of Obstetricians and Gynecologists et al. v. U.S. Food and Drug Administration et al., No. 8:20-cv-1320-TDC (D. Md.)

Dear Judge Chuang:

Defendants respectfully submit this letter in response to Plaintiffs' June 26, 2020 letter, Dkt. 79, regarding a decision of the U.S. Court of Appeals for the Eleventh Circuit, *People First of Alabama v. Secretary of State for the State of Alabama*, No. 20-12184 (11th Cir. June 25, 2020), Dkt. 79-1. In *People First*, the Eleventh Circuit declined to stay an order of the Northern District of Alabama preliminarily enjoining Alabama election officials from enforcing certain absentee ballot requirements or acting to restrict curbside voting for an upcoming primary election in light of COVID-19. *See* Dkt. 79-1, at 9-10 (Rosenbaum and Jill Pryor, JJ., concurring). Plaintiffs assert that *People First*—which is not binding on this Court—"is analogous to the case at bar on both the facts and the law." Dkt. 79, at 1. This is wrong for multiple reasons.

First, People First is a voting case, not an abortion case. Thus, it applied an entirely different set of rules and precedents. Among other things, there is no "substantial obstacle" requirement in the voting rights context, nor does the "undue burden" standard apply. See Dkt. 79-1, at 16 ("A 'flexible standard' applies to constitutional challenges to specific provisions of a state's election laws." (quoting Common Cause/Georgia v. Billups, 554 F.3d 1340, 1352 (11th Cir. 2009)). Rather, the court in *People First* applied a freestanding benefits-burdens analysis. *See id.* at 17-21. In the abortion context, by contrast, every member of the Supreme Court emphasized just this week the importance of demonstrating that a law poses a "substantial obstacle" to abortion access in order to obtain relief. See June Medical Servs., LLC v. Russo, No. 18-1323, 2020 WL 3492640, at \*4, \*7, \*10, \*12, \*20 (U.S. June 29, 2020) (plurality op.) (analyzing whether challenged law posed a substantial obstacle to abortion access); id. at \*23-26 (Roberts, C.J., concurring in the judgment) (same); id. at \*38-39 (Alito, J., joined by Thomas, Gorsuch, and Kavanaugh, JJ., dissenting) (same); see also Defs.' Mem. in Opp. to Pls.' Mot. for Prel. Inj., Dkt. 62, at 13-14 (citing cases). Here, the Mifeprex in-person dispensing requirement is not a substantial obstacle to a large fraction of women seeking an abortion. See Dkt. 62, at 13-21. That alone defeats Plaintiffs' due process claim. See id. at 22.

Second, the comparative benefits and burdens of the challenged laws in *People First* and in this case are quite different. As to the benefits, in *People First*, the district court found that the problem the challenged election laws targeted—voter fraud—was "nearly non-existent," and that

the laws in any event did "little" to "protect[] against" that problem. *See* Dkt. 79-1, at 20. Here, by contrast, use of Mifeprex carries severe and even life-threatening risks that require surgical intervention in up to 7 percent of patients who use the drug, Compl. Ex. 1, Dkt. 1-3, at 17, and FDA has determined, in the exercise of its expert scientific judgment, that the Mifeprex REMS, including the in-person dispensing requirement, is "necessary" to mitigate those risks, *see* Dkt. 62, at 5-6. As to the burdens, in *People First*, the plaintiffs were at "higher risk of contracting a severe case of [COVID-19] because of their ages, races, or underlying medical conditions." Dkt. 79-1, at 4. In this case, by contrast, the relevant demographic—women of child-bearing age—are at *lower* risk of serious injury from COVID-19. *See* CDC, *People Who are at Higher Risk for Severe Illness*, https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-at-higher-risk.html (last accessed June 9, 2020). So the benefits of the challenged law in this case are stronger than the asserted benefits in *People First*, while the alleged burdens are weaker. Moreover, in preliminarily enjoining the state election officials in *People First*, the district court in that case "narrow[1y]" tailored its order so that it "appl[ied] to only high-risk" individuals. Dkt. 79-1, at 9. Plaintiffs seek no such limitation here.

Third, in People First, the Eleventh Circuit appeared to presume that absent an injunction, at least some otherwise qualified voters would be unable to "cast a vote." Dkt 79-1, at 24. Here, by contrast, Plaintiffs have not submitted any evidence demonstrating that the in-person dispensing requirement will prevent any patients from obtaining an abortion, nor could they. See Dkt. 62, at 18-19. The requirement applies only to one type of procedure—medication abortion using Mifeprex or its generic—and does not impact any other methods through which patients may obtain an abortion. Id. at 14-15.

In sum, People First does not support Plaintiffs' claims.

Very truly yours,

GUSTAV W. EYLER
Director
Consumer Protection Branch
Civil Division

By: /s/ Hilary K. Perkins
Hilary K. Perkins
Trial Attorney
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cc (via CM/ECF): Counsel of Record

## **CERTIFICATE OF SERVICE**

I certify that on July 1, 2020, I served a copy of this correspondence by filing it with the Court's CM/ECF system, which transmits a copy to all registered parties.

/s/ Hilary K. Perkins
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